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APPLICATION NO.	FILING DATE	FIRST NAME (FINGERPRINT)	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,695	06/08/2001	Yoshinobu Kiso	46-219	1040

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EXAMINER

KHARE, DEVESH

ART UNIT PAPER NUMBER

1623

DATE MAILED: 05/06/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

Applicant(s)

09/857 695

KISO ET AL.

**Office Action Summary**

Examiner

Art Unit

Devesh Khare

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

**35 U.S.C. 112, second paragraph rejection**

**Claims 3,4,7-11 and 12** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4,8 and 12, the pharmaceutically acceptable carrier is not defined, rendering the claim incomplete. The phrase "a pharmaceutically acceptable carrier" is ambiguous and renders claims 4,8 and 12 indefinite.

Claims 3,7 and 11 are unclear with regard to the terms "atleast 30%".

Claims 3,7 and 11 are directed to a therapeutic agent. It is unclear whether the term "atleast 30%" refer to a specific unit.

Claims 8-10 are directed to the therapeutic agent which contains xylooligosaccharide containing xylobiose in claim 2. Claims 8-10 does not confer patentable distinction on the previously claimed therapeutic agent claim therefore claims 8-10 are being a substantial duplicate of claim 2.

**35 U.S.C. 101 reads as follows:**

*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

**Claims 13-18** are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C.

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101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.1967) and *Clinical Products, Ltd. V. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

**35 U.S.C. 102(b) rejection**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless --*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

***Claims 1-12 are rejected*** under 35 U.S.C. 102(b) as being anticipated by

Mitsuhashi et al. (EP 382355).

The applicants claims are broadly directed toward a therapeutic agent xylobiose or xylooligosaccharide for the treatment of hyperammonemia or hepatic encephalopathy that need be administered in smaller doses.

Mitsuhashi et al. discloses the oral administration of xylooligosaccharide in the treatment of hyperammonemia and hepatic encephalopathy. Mitsuhashi et al. discloses further the weight ratio of xylooligosaccharide to a pharmaceutically carrier in the range of about 0.1-10, on a dry solid basis which is encompassed by the applicants claims (see abstract and claims 5,6,7 and 14).

**State of the Art References**

The following references further reflect the current state of the art:


Rikkers (Abstract: Surgery (1983 Aug.) 94(2),pp 126-133) – Discloses the assessment of portal hemodynamics, intestinal absorption of D-xylose, ammonia metabolism, and clinical encephalopathy.

Pai et al.(Abstract : Chinese Medical Journal, 1995 Jan., 55(1), pp. 31-36) – Discloses Lactitol an analogue of lactulose as an alternative to lactulose in the treatment of portosystemic encephalopathy.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devesh Khare whose telephone number is (703)605-1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (703)308-4532. The official fax phone numbers for the organization where this application or proceeding is assigned is (703)308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

  
Devesh Khare, Ph.D.,JD(2Y).  
Art Unit 1623  
May 2,2002

